IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF OKLAHOMA

SHANNA CLARK, Plaintiff, vs. ANGIODYNAMICS, INC., & NAVILYST MEDICAL, INC., Defendants.	Case No.: CIV-24-764-D **COMPLAINT FOR DAMAGES** **(1) NEGLIGENCE** **(2) FAILURE TO WARN** **(3) DESIGN DEFECT** **(4) BREACH OF IMPLIED WARRANTY** **(5) BREACH OF EXPRESS WARRANTY** **(6) FRAUDULENT CONCEALMENT** **(7) OKLAHOMA'S CONSUMER PROTECTION ACT (OCPA)** **DEMAND FOR JURY TRIAL**

COMPLAINT

COMES NOW Plaintiff, Shanna Clark, (hereinafter "Plaintiff"), by and through her undersigned counsel, and brings this Complaint against AngioDynamics, Inc., and Navilyst Medical, Inc., (collectively, the "Defendants"), and alleges as follows:

1. This is an action for damages arising out of failures relating to Defendants' design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling the defective implantable vascular access device sold under the trade name of BioFlo Port with ENDEXO Technology (hereinafter "BioFlo" or "Defective Device").

PARTIES

2. Plaintiff, Shanna Clark is an adult resident and citizen of Stephens County, Oklahoma, and claims damages as set forth below.

3. Defendant AngioDynamics, Inc. ("AngioDynamics") is a Delaware corporation with its principal place of business located in Latham, New York. AngioDynamics is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the BioFlo.

4. Defendant Navilyst Medical, Inc. ("Navilyst") is a Delaware corporation with its principal place of business located in Marlborough, Massachusetts. Navilyst conducts business throughout the United States, including the State of Oklahoma, and is a wholly owned subsidiary of AngioDynamics. Navilyst is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the BioFlo.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

6. Venue is proper in this Court pursuant to 28 U.S.C. §1391 by virtue of the facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District, and (b) Defendants' products are produced, sold to, and consumed by individuals in the State of Oklahoma, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

7. Defendants have and continue to conduct substantial business in the State of

Oklahoma and in this District, distribute vascular access products in this District, receive substantial compensation and profits from sales of vascular access products in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

8. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants because Defendants are present in the State of Oklahoma, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

PRODUCT BACKGROUND

9. In or about 2013, Defendants received clearance via the 501(k) Premarket Notification Program from the Food and Drug Administration (FDA) to market and sell BioFlo.

10. Defendants' Vascular Access Devices were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendants at all relevant times herein.

11. The BioFlo is one of several varieties of port/catheter systems that has been designed, manufactured, marketed, and sold by Defendants.

12. According to Defendants, the BioFlo is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products.

13. The intended purpose of the BioFlo is to make it easier to deliver medications directly into the patient's bloodstream. The device is surgically placed completely under the skin and left implanted.

14. The BioFlo is a system consisting of two primary components: an injection port and a polyurethane catheter which includes additives intended to make it radiopaque and anti-thrombogenic.

15. The injection port has a raised center, or "septum," where the needle is inserted for delivery of the medication. The medication is carried from the port into the bloodstream through a small, flexible tube, called a catheter, that is inserted into a blood vessel.

16. The BioFlo is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

17. The product's catheter is comprised of a polymeric mixture of polyurethane, a barium sulfate radiopacity agent, and a low molecular weight fluorinated additive intended to reduce formation of blood clots.

18. Barium sulfate is known to contribute to reduction of the mechanical integrity of polyurethane *in vivo* as the particles of barium sulfate dissociate from the surface of the catheter over time, leaving microfractures and other alterations of the polymeric structure and degrading the mechanical properties of the polyurethane.

19. Researchers have shown that catheter surface degradation in products featuring a radiopaque barium sulfate stripe is concentrated at the locus of the stripe.[1]

20. The mechanical integrity of a barium sulfate-impregnated silicone is affected by the concentration of barium sulfate as well as the heterogeneity of the modified polymer.

[1] See Hecker JF, Scandrett LA. Roughness and thrombogenicity of the outer surfaces of intravascular catheters. *J Biomed Mater Res*. 1985;19(4):381-395. doi:10.1002/jbm.820190404

21. Upon information and belief, Defendants' manufacturing process in designing and constructing the catheter implanted in Plaintiff involved too high a concentration of barium sulfate particles for the polymer formulation, leading to improperly high viscosity of the admixed polyurethane before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix.

22. This defect in the manufacturing process led to a heterogeneous modified polymer which included weakened areas at the loci of higher barium sulfate concentration and led to fracture of the catheter.

23. Although the surface degradation and resultant mechanical failure can be reduced or avoided with design modifications (e.g., using a higher grade radiopacity compound and/or encapsulating the admixed polymer within polyurethane), Defendants elected not to incorporate those design elements into the BioFlo.

24. At all times relevant, Defendants misrepresented the safety of the BioFlo system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the BioFlo system as safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.

25. Defendants obtained "clearance" to market these products under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

26. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the device. The FDA explained the difference between the 510(k) process and

the more rigorous "premarket approval" ("PMA") process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, which the court quoted from:

> A manufacturer can obtain an FDA findings of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by the FDA (as opposed to "approved' by the agency under a PMA.
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> 376 F.3d 163, 167 (3d. Cir. 2004).

27. A pre-market notification submitted under 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate that the product involved is safe and effective.

28. In *Medtronic, Inc.* v. Lohr, the U.S. Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…. The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in average of 20 hours …. As one commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits a negative response form the FDA, and gets processed quickly.
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> 518 U.S. 470, 478-79 (1996).

29. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse associated with the drug…and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling …." This obligation extends to post-market monitoring of adverse events/complaints.

30. At all times relevant to this action, Defendants misrepresented the safety of the

BioFlo system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the BioFlo system as safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.

31. At all times relevant to this action, Defendants knew and had reason to know, that the BioFlo was not safe for the patients for whom they were prescribed and implanted, because once implanted the device was prone to fracturing, migrating, perforating internal vasculature, and otherwise malfunctioning.

32. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with a BioFlo port had an increased risk of suffering life threatening injuries, including but not limited to: death; infection; fracture; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.

33. Soon after the BioFlo was introduced to market, which was years before Plaintiff was implanted with her device, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the BioFlo was fracturing post-implantation and that fractured pieces were migrating throughout the human body, including to the heart and lungs. Defendants also received large numbers of AERs reporting that the BioFlo was found to have perforated internal vasculature. These failures were often associated with reports of severe patient injuries such as:

a. hemorrhage;

b. fracture;

c. cardiac/pericardial tamponade;

d. cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. severe and persistent pain;

f. perforations of tissue, vessels and organs; and

g. upon information and belief, even death.

34. In addition to the large number of AERs which were known to Defendants and reflected in publicly accessible databases, there are many recorded device failures and/or injuries related to the Defendants' implantable port products which were concealed from medical professionals and patients through submission to the FDA's controversial Alternative Summary Reporting ("ASR") program.

35. The FDA halted the ASR program after its existence was exposed by a multi-part investigative piece, prompting a widespread outcry from medical professionals and patient advocacy groups.[2]

36. Prior to the discontinuation of the ASR program, Defendants reported numerous episodes of failures of their implanted port/catheter products – including episodes of catheter fracture and leakage, blood clot formation post-implantation, and infection – under the ASR exemption, thereby concealing them from physicians and patients.

37. Defendants were aware or should have been aware that the BioFlo had a substantially higher failure rate than other similar products on the market, yet Defendants failed to

[2] Christina Jewett, *Hidden Harm: Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, Kaiser Health News (Mar. 2019)

warn consumers of this fact.

38. Defendants also intentionally concealed the severity of complications caused by the BioFlo and the likelihood of these events occurring. This included, but was not limited to, knowledge that a fracture of the BioFlo could lead to leakage of chemotherapy medicine which can cause infection and necrosis of the surrounding tissue in the area of the BioFlo port, and that the BioFlo can cause blood clots, including pulmonary embolisms which can be deadly.

39. Rather than alter the design of the BioFlo to make it safer or adequately warn physicians of the dangers associated with the BioFlo, Defendants continued to actively and aggressively market the BioFlo as safe, despite their knowledge of numerous reports of catheter fracture and associated injuries.

40. Multiple feasible alternative designs for the BioFlo have been available to Defendants at all times relevant to this matter.

41. Moreover, Defendants' warnings suggested that fracture of the device could only occur if the physician incorrectly placed the device such that undue catheter compression or "pinch-off" was allowed to occur. In reality, Defendants knew internally these devices were fracturing and causing serious injuries due to defects in the design, manufacturing and lack of adequate warnings.

42. The conduct of Defendants, as alleged in this Complaint, constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff and evidences malice, fraud, gross negligence, and oppressiveness. Defendants had actual knowledge of the dangers presented by the BioFlo System, yet consciously failed to act reasonably to:

a. Adequately inform or warn Plaintiff, her prescribing physicians, or the public at large of these dangers;
b. Establish and maintain an adequate quality and post-market surveillance system; or
c. Recall the BioFlo System from the market.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

43. On or about July 14, 2021, Plaintiff underwent placement of an AngioDynamics BioFlo product. The device was implanted by Dr. Dustin C. Woods, M.D., at Duncan Regional Hospital in Duncan, Oklahoma, for the purpose of frequent IV access.

44. Defendants, directly or through their agents, apparent agents, servants, or employees designed, manufactured, marketed, advertised, distributed and sold the BioFlo that was implanted in Plaintiff.

45. Defendant manufactured, sold, and/or distributed the BioFlo to Plaintiff, through her doctors, to be used for purpose of frequent IV access.

46. On or about July 29, 2022, Plaintiff presented herself to Duncan Regional Hospital due to persistent pain and tenderness associated with the BioFlo. Plaintiff underwent a port check which demonstrated a fracture in the catheter line of the defective device with free extravasation into the soft tissues.

47. At all times, the BioFlo was utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use and created procedures for implanting the product.

48. The BioFlo implanted in Plaintiff was in the same or substantially similar condition as when it left the possession of Defendants and in the condition directed by and expected by Defendants.

49. Plaintiff and her physicians foreseeably used and implanted the BioFlo and did not misuse or alter the BioFlo in an unforeseeable manner.

50. Defendants advertised, promoted, marketed, sold, and distributed the BioFlo as a safe medical device when Defendant knew or should have known the BioFlo was not safe for its intended purposes and that the product could cause serious medical problems.

51. Defendants had sole access to material facts concerning the defective nature of the BioFlo product and its propensity to cause serious and dangerous side effects.

52. In reliance on Defendants' representations, Plaintiff's doctors were induced to, and did use the BioFlo.

53. As a result of having the BioFlo implanted, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone corrective surgeries, and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

54. Defendants' BioFlo was marketed to the medical community and to patients as a safe, effective, reliable, medical devices implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, and as safer and more effective as compared to the traditional products and procedures for treatment and other competing Vascular Access Devices.

55. The Defendants have marketed and sold the Defendants' BioFlo to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, direct to consumer

advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or group purchasing organizations, and include a provision of valuable consideration and benefits to the aforementioned.

56. The injuries, conditions, and complications suffered due to Defendants' BioFlo include, but are not limited to, fracture and leakage; necrosis; infection; blood clots; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels and organs; and even death.

57. Defendants were negligent toward Plaintiff in the following respects:

a. Defendant failed to design and establish a safe, effective procedure for removal of BioFlo; therefore, in the event of a failure, injury, or complications it is difficult to safely remove BioFlo.

b. Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using BioFlo for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including the Plaintiff.

58. The BioFlo was utilized and implanted in a manner foreseeable to Defendants.

59. The BioFlo implanted into Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants and in the condition directed by the Defendants.

60. At the time of her operation, Plaintiff was not informed of, and had no knowledge of the complaints, known complications, and risks associated with BioFlo, including, but not limited to its propensity to fracture and leak and the various complications associated with leakage of chemotherapy medication.

61. Plaintiff was never informed by Defendants of the defective and dangerous nature

of BioFlo.

62. At the time of her implant, neither Plaintiff nor Plaintiff's physicians were aware of the defective and dangerous condition of the BioFlo.

63. Plaintiff has suffered and will continue to suffer physical pain and mental anguish.

64. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective product that was implanted in her body.

COUNT I: NEGLIGENCE
(Against Defendants AngioDynamics and Navilyst)

65. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

66. The Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling, conducting post-market surveillance of the BioFlo, and recruitment and training of physicians to implant the BioFlo.

67. The Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

a. Failing to properly and thoroughly test the BioFlo before releasing the device to market, and/or failing to implement feasible safety improvements;

b. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the BioFlo;

c. Failing to conduct sufficient post-market testing and surveillance of the BioFlo;

d. Failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the BioFlo;

e. Designing, manufacturing, marketing, advertising, distributing, and selling the

BioFlo to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the BioFlo, including, but not limited to, its propensity to fracture and leak, and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;

f. Failing to exercise due care when advertising and promoting the BioFlo; and

g. Negligently continuing to manufacture, market, advertise, and distribute the BioFlo after Defendants knew or should have known of its adverse effects.

68. As a direct, actual, and proximate cause of the Defendants' actions, omissions, and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe injuries and complications which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

69. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted grossly negligent, fraudulently, and with malice.

COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Against Defendants AngioDynamics and Navilyst)

70. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

71. Defendant supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the BioFlo implanted into Plaintiff.

72. The BioFlo implanted in Plaintiff was not reasonably safe for its intended use and was defective with respect to its design.

73. The product was defective in its design in that when it left the hands of Defendant,

it was not safe for its anticipated use and safer, more reasonable alternative designs existed that could have been utilized by Defendant.

74. The BioFlo was in a defective condition at the time that it left the possession or control of Defendants.

75. A reasonably prudent medical device manufacturer would not have placed the BioFlo with its defective design into the stream of commerce.

76. The BioFlo was defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce and when it was implanted in Plaintiff.

77. The BioFlo was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in its use. The foreseeable risks associated with the design of the product were more dangerous than a reasonably prudent consumer such as Plaintiff and/or his physician would expect when the product was used for its normal and intended purpose.

78. The BioFlo reached Plaintiff's implanting surgeon and was implanted in Plaintiff without any substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.

79. The BioFlo failed to perform as safely as an ordinary consumer and/or his physician would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, and the risks and dangers of the BioFlo outweigh its benefits.

80. The design defects in the BioFlo were not known, knowable and/or reasonably apparent to Plaintiff and/or his physician or discoverable upon any reasonable examination.

81. The BioFlo was used and implanted in the manner in which it was intended to be used and implanted by Defendants pursuant to the instructions for use and the product

specifications provided by Defendants.

82. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling a defective product.

83. As a direct and proximate result of the BioFlo's aforementioned defects, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

COUNT III: STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(Against Defendants AngioDynamics and Navilyst)

84. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

85. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the BioFlo, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers, and therefore had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

86. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, the device was defective and presented a substantial danger to users of the product when put to its intended and reasonably anticipated use, namely as an implanted port/catheter system to administer the medications.

87. Defendants failed to adequately warn of the device's known or reasonably scientifically knowable dangerous propensities and further failed to adequately provide

instructions on the safe and proper use of the device.

88. Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the BioFlo that was implanted into Plaintiff that the BioFlo posed a significant and higher risk than other similar devices of device failure and resulting serious injuries.

89. Defendants further knew that these devices were fracturing and leaking for reasons other than "pinch-off" caused by the physician's initial placement of the device.

90. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the BioFlo; no reasonable health care provider, including Plaintiff's, and no reasonable patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers or the consumers of the device.

91. The warnings, labels, and instructions provided by the Defendants at all time relevant to this action, are and were inaccurate, intentionally misleading, and misinformed and misrepresented the risks and benefits and lack of safety and efficacy associated with the device.

92. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

93. The BioFlo, which was designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by Defendants, was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

94. When Plaintiff was implanted with the device, Defendants failed to provide adequate warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, as discussed herein.

95. Defendants intentionally underreported the number and nature of adverse events associated with fracture of the devices to Plaintiff's health care providers, as well as the FDA.

96. Neither Plaintiff nor her health care providers knew of the substantial danger associated with the intended and foreseeable use of the device as described herein.

97. Plaintiff and her health care providers used the BioFlo in a normal, customary, intended, and foreseeable manner, namely as a surgically placed device used to make it easier to deliver medications directly into the patient's bloodstream. Moreover, Plaintiff's health care providers did not place or maintain the device incorrectly such that it caused the device to "pinch off" or otherwise malfunction.

98. Upon information and belief, the defective and dangerous condition of the device, including the one implanted into Plaintiff, existed at the time they were manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold by Defendants to distributors and/or healthcare professionals or organizations.

99. Upon information and belief, the device implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

100. Defendants' lack of sufficient warning and/or instructions was the direct and proximate cause of Plaintiff's serious physical injuries, and economic damages in an amount to be determined at trial. In other words, had Defendants provided adequate warnings, Plaintiff and her physicians would not have used the device.

COUNT IV: BREACH OF IMPLIED WARRANTY

(Against Defendants AngioDynamics and Navilyst)

101. Plaintiff incorporates preceding paragraphs as if set out fully herein.

102. Defendants impliedly warranted that the BioFlo was merchantable and fit for the ordinary purposes for which it was intended.

103. When the BioFlo was implanted in the Plaintiff, it was being used for the ordinary purposes for which it was intended.

104. The Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the BioFlo implanted in her.

105. Privity exists between Plaintiff because Plaintiff's physicians acted as Plaintiff's purchasing agents in the subject transaction and/or because Plaintiff was a third-party beneficiary of the subject contract.

106. Plaintiff was intended consumer of the device when Defendant made the warranties set forth herein, and such warranties were made to benefit Plaintiff as a patient and consumer.

107. Defendants breached these implied warranties of merchantability because the BioFlo implanted in Plaintiff was neither merchantable nor suited for its intended uses as warranted in that the device varied from its intended specifications, which included, but are not limited to, variances in the following respects:

a. Defendants' manufacturing process in constructing the catheter of the BioFlo implanted in Plaintiff involved too high of a concentration of barium sulfate particles for the polymer formulation, which led to improperly high viscosity of the admixed polyurethane before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix;

b. Defendants' knew or should have known barium sulfate is known to contribute to a reduction in the mechanical integrity of the polyurethane in its product, the BioFlo, as the barium sulfate particles dissociate from the surface of the catheter over time; and

c. These defects led to a heterogenous modified polymer that included microfractures and weakened areas at the location of the higher barium sulfate concentration that ultimately led to fractures of the BioFlo and associated injuries.

d. Defendants represented to Plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' BioFlo was of merchantable quality and safe when used for its intended purpose meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using BioFlo;

e. Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendants' BioFlo was safe, as safe as and/or safer than other alternative procedures and devices, meanwhile Defendant fraudulently concealed information, which demonstrated that the BioFlo was not safe, as safe as or safer than alternatives and other products available on the market; and

f. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' BioFlo was more efficacious than other alternative procedures and/or devices. Meanwhile Defendant fraudulently concealed information,

regarding the true efficacy of the BioFlo product.

108. Defendants' breaches of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product, the BioFlo, into Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

109. The BioFlo was sold to Plaintiff's health care providers for implantation in patients, such as Plaintiff.

110. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff suffered severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages. These damages have occurred in the past and will continue into the future.

111. Upon information and belief, Plaintiff's healthcare providers sent notice to Defendants of the adverse event that occurred to Plaintiff and thus, the nonconformity of the BioFlo, within a reasonable period of time following discovery of the breach of warranty and before suit was filed.

COUNT V: BREACH OF EXPRESS WARRANTY
(Against Defendants AngioDynamics and Navilyst)

112. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

113. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the BioFlo was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

114. The BioFlo does not conform to the Defendants' express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and permanent injury.

114. Defendants further breached express representations and warranties made to Plaintiff, her physicians and healthcare providers with respect to the BioFlo implanted in Plaintiff in the following respects:

a. Defendant represented to Plaintiff and his physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' BioFlo was safe, meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using BioFlo;

b. Defendant represented to Plaintiff and his physicians and healthcare providers that the Defendants' BioFlo was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendant fraudulently concealed information that demonstrated that BioFlo was not safer than alternative therapies and products available on the market; and

c. Defendant represented to Plaintiff and his physicians and healthcare providers that the Defendants' BioFlo was more efficacious than other alternative procedures, therapies and/or devices. Meanwhile Defendant fraudulently concealed information, regarding the true efficacy of BioFlo.

115. At all relevant times, the BioFlo did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

116. Plaintiff, her physicians, and the medical community reasonably relied upon the Defendants' express warranties for the BioFlo.

117. Privity exists between Plaintiff because Plaintiff's physicians acted as Plaintiff's purchasing agents in the subject transaction and/or because Plaintiff was a third-party beneficiary of the subject contract.

118. Plaintiff was the intended consumer of the device when Defendant made the warranties set forth herein, and such warranties were made to benefit Plaintiff as a patient and consumer.

119. At all relevant times, the BioFlo was used on Plaintiff by Plaintiff's physicians for the purpose and in the manner intended by Defendants.

120. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

121. As a direct and proximate result of the breach of Defendants' express warranties, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

122. Upon information and belief, Plaintiff's healthcare providers sent notice to Defendants of the adverse event that occurred to Plaintiff and thus, the nonconformity of the BioFlo, within a reasonable period of time following discovery of the breach of warranty and before suit was filed.

COUNT VI: FRAUDULENT CONCEALMENT

(Against Defendants AngioDynamics and Navilyst)

123. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

124. Defendants made false statements and representations to Plaintiff and her healthcare providers concerning the BioFlo product implanted in Plaintiff.

125. Defendants engaged in and fraudulently concealed information with respect to the BioFlo in the following respects:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the BioFlo was safe and fraudulently withheld and concealed information about the substantial risks of using the BioFlo, including but not limited to, its heightened propensity to fracture, leak, and cause complications, including necrosis, infection, and blood clots;

b. Defendants represented that the BioFlo was safer than other alternative systems and fraudulently concealed information which demonstrated that the BioFlo was not safer than alternatives available on the market;

c. Defendants concealed that it knew these devices were fracturing and causing complications from causes other than the manner in which the implanting physician implanted the device; and

d. Defendants knew that neither Medicare, Medicade, nor most private insurance entities offer reimbursement for medical devices which aren't approved or cleared by the FDA; and

e. That frequency of these failures and the severity of injuries were substantially

worse than had been reported.

126. Defendants had knowledge that the representations they made concerning the BioFlo, as stated above, were false.

127. Defendants had sole access to material facts concerning the dangers and unreasonable risks of the BioFlo.

128. The concealment of information by the Defendants about the risks of the BioFlo was intentional.

129. The concealment of information and the misrepresentations about the BioFlo was made by the Defendants with the intent that Plaintiff's health care providers and Plaintiff rely upon them.

130. Plaintiff and her physicians relied upon the representations and were unaware of the substantial risks of the BioFlo which the Defendants concealed from the public, including Plaintiff and her physicians.

131. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

132. The Defendants acted with oppression, fraud, and malice towards Plaintiff.

133. Had Defendants not concealed this information, neither Plaintiff's nor her health care providers would have consented to using the device in Plaintiff.

COUNT VII: OKLAHOMA'S CONSUMER PROTECTION ACT

(Against Defendants AngioDynamics and Navilyst)

134. Plaintiff incorporates the preceding paragraphs as if set out fully herein.

135. Plaintiff purchased the BioFlo, and the product was intended for personal use.

136. The acts and practices engaged in by Defendants as outlined above constitute unlawful, unfair, and/or fraudulent business practices in violation of the Oklahoma Consumer Protection Act, (OCPA), O.S. tit. 15, § 751, *et seq*.

137. This included, but was not limited to, representing that BioFlo has characteristics or benefits it did not have and/or misrepresenting that the BioFo was of a particular standard, namely, that it was reasonably safe for use when it was not.

138. Defendants engaged in unlawful practices including deception, false promises, misrepresentation, and/or the concealment, suppression, or omission of material facts in connection with the sale, distribution, and/or advertisement of the BioFlo in violation of O.S. tit. 15, § 753.

139. Defendants further knowingly or recklessly engaged in unfair, unconscionable, deceptive, deliberately misleading, false, and/or fraudulent and deceptive acts and practices, all in violation of the OCPA, and as further described herein, which created a likelihood of confusion or misunderstanding on Plaintiff's part with respect to the BioFlo she purchase, including, but not limited to, misrepresenting that the BioFlo was reasonably safe for use and failing to adequately disclose the substantial risk of fracture and harm the product entailed given the large number of adverse events Defendants knew or should have been aware of but did not adequately disclose to Plaintiff.

140. Defendants' practices were likely to mislead consumers who acted reasonably to

their detriment in purchasing the product based on Defendants' representations that it was reasonably safe for use when it in fact was not and had a higher risk of fracture due to its defective design.

141. Defendants intended for Plaintiff, Plaintiff's physicians, and other consumers to rely on their deceptive practices and representations in order to continue selling and manufacturing the BioFlo.

142. Plaintiff purchased the BioFlo, a product that was falsely represented, as set out above, in violation of the Oklahoma Consumer Protection Act, and as a result Plaintiff suffered economic damages in that the product purchased was misrepresented to be reasonably safe for use and was worth less than the product Plaintiff thought she had purchased had Defendants' representations been true.

PRAYER

WHEREFORE, Plaintiff prays for judgment against each of the Defendants as follows:

a. Judgment be entered against all Defendant on all causes of action of this Complaint;

b. Plaintiff be awarded her full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded general damages according to proof at the time of trial;

d. Plaintiff be awarded damages, including past, present, and future, medical expenses according to proof at the time of trial;

e. Plaintiff be awarded costs and attorney's fees in connection with Plaintiff's Oklahoma Consumer Protection Act (OCPA) claim under O.S. tit. 15, § 751, *et seq*., and O.S. tit. 15, § 761.1;

f. Awarding pre-judgment and post-judgment interest to the Plaintiff;

g. Awarding the costs and the expenses of this litigation to the Plaintiff;

h. For such other and further relief as the court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Respectfully submitted,

/s/ Austin C. Walters
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